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EXAMINER	
KLINKEL, KORTNEY L	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,785	MOULINOUX ET AL.	
	Examiner	Art Unit	
	Kortney L. Klinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 13-32* is/are pending in the application.

4a) Of the above claim(s) *17-22, 28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-16,23-27,29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claims 1 and 13-32 are pending in the instant Office action. Claims 2-12 stand canceled. Claims 1, 14 and 15 were amended. Claims 17-22, 28 and 30 remain withdrawn for being directed to non-elected subject matter. Claims 1, 13-16, 23-27, 29 and 31-32 are under examination to the extend that they read on the embodiment having no inhibitor of intercellular synthesis or polyamines, no antibiotic and no vitamins as well as the syndrome or pathology in which the NR2-B subunit of the N-methyl-D-aspartate (NMDA) receptor is involved.

Claim Rejections - 35 USC § 112 2nd Paragraph—Withdrawn

The rejection of claims 1 and 13-15 and thereby dependent claims 31-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for not providing a positive definition of the subject matter for which patent protection is sought is withdrawn in light of the claim amendments.

The rejection of claims 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for containing broad limitations followed by more narrow limitations is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112 1st Paragraph—Withdrawn

The rejection of claims 1 and 13-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the claim amendments. The claims now provide a positive recitation of the composition to be administered.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-15 list the negative limitations of the amounts of the various polyamines in the following way: less than about X picomoles/g. The metes and bounds of these negative limitations are unclear. There is no clear upper boundary conveyed by the claims. The phrase “less than” requires the amount to be less than X but the word "about” includes values larger than X. The two phrases contradict one another. Additionally, there is no clear definition of the word “about” in the instant specification so it is also unclear how far reaching the term “about” truly is.

Claims 27 and 29 recite the limitation “sufficient quantities of vitamins, minerals and electrolytes to satisfy the daily nutritional needs of a human being.” It is unclear

what quantities of vitamins, minerals and electrolytes are required by these claims. As such, the metes and bounds of these claims are unclear.

Response to Arguments

Applicant's arguments regarding the rejection of claims under 35 U.S.C. 112, second paragraph have been fully considered, but are not persuasive. Regarding the rejection of claims 13-15, Applicant argues that the term "about" merely extends some flexibility to the number. Applicant argues that for example 401 picomoles literally is not less than 400, but that a person of ordinary skill in the art would equate this to being about 400. Applicant points to MPEP 2173.05(b)(A) which discusses that between 20 to about 45 % was held to be clear, but flexible. These arguments are not persuasive. The fact pattern present in the example in MPEP 2173.05(b)(A) is not similar to the fact pattern of the instant case. The MPEP example only uses the modifier "about", not "less than" in conjunction with "about". As argued by applicant, the recitation of about 400 picomoles could mean 401 picomoles, but then "less than" suggests an amount less than 400 picomoles. Thus the recitation of less than about 400 picomoles suggests conflicting boundaries. The Applicant is requested to note that the Federal Circuit in *Amgen, Inc. v. Chugai*, 927 F.2d at 1200, 1218 (Fed. Cir. 1991), held that a word of degree can be indefinite when it fails to distinguish the invention over the prior art and does not permit one of ordinary skill to know what activity constitutes infringement. The recitation "at least about 160,000" has been held indefinite. *Id.* at 1203.

Regarding the rejection of claims 27 and 29, applicant argues that the metes and bounds of these claims are clear to a person of ordinary skill in the art, but does not

specifically point out an error in the Examiner's rejection. It is unclear what quantities of vitamins, minerals and electrolytes are required by these claims. It is unclear exactly what is meant by the phrase "daily nutritional needs of a human being". Is this the amount necessary to thrive, or the amount necessary to stave off death? As the phrase "daily nutritional needs of a human being" is an ambiguous term, it is unclear what quantity of the recited vitamins, minerals and electrolytes are desired. It is unclear if applicant intends to obtain patent protection for all vitamins, a few vitamins, all minerals, a few minerals, all electrolytes or a few electrolytes. In summary it is unclear which ingredients and what amount of these ingredients are encompassed by the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13-16, 23-27, 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Moulinoux et al. (CA 2165481, which is the English language equivalent of WO 95/00041, as per Applicant's IDS).

Note that this rejection has only been modified to the extent necessary to address the newly added claim limitations. The preamble, composition and functional outcome of administering the composition have all been modified.

Moulinoux et al. teach a composition that can be ingested by man which contains less than about 1600 picomoles/g of polyamine (p. 5, lines 15-17). It can also be in the form of a daily food ration (p. 10, lines 13-15). More specifically this composition which can be administered to man preferably contains less than about 50 picomoles/g of putrescine, spermidine, spermine and cadaverine respectively (p. 5, lines 27-34). The composition which is to be administered further comprises 10-35% lipids, 8-30% proteins, 35-80% glucides and up to 10% of a mixture composed of vitamins, minerals and electrolytes as a percentage of dry weight with respect to the total composition (p. 6, lines 5-10). More specifically, the preferred glucides are glucose polymers, maltodextrines, saccharose, modified starches, monohydrated glucose, dehydrated glucose syrup, glycerol monostearate and mixtures of these substances (p. 9, lines 27-31). The preferred proteins are soluble milk proteins, soya proteins, serum peptides, powdered egg yolk, potassium caseinate, unphosphorylated peptides, casein peptides, mixed caseinate, soya isolate and mixtures of these substances (p. 10, lines 1-6). The preferred lipids are butter oil, peanut oil, medium chain triglycerides, grape pip oil, soya oil, onager oil and mixtures of these oils and the lipids are advantageously composed of a mixture of at least one animal oil, at least one vegetable oil and glycerol stearate (p. 10, lines 7-12). With respect to claims 31-32, the composition to be administered may be in dry form to be dissolved extemporaneously in a neutral vehicle suitable for oral or enteral administration (p. 6, lines 11-14).

With respect to claim 27, Moulinoux et al. teach that the composition to be administered forms a daily food ration for one person and includes

- between 75 g and 500 g of glucides,

- between 20 g and 185 g of lipids,

- between 20 g and 225 g of proteins,

- sufficient quantities of vitamins, minerals and electrolytes to satisfy the daily nutritional needs of a human being (p. 10, lines 15-24). This composition is taught to reduce intracellular synthesis and external input of polyamines (p. 10, lines 32-35).

With respect to claim 29, Moulinoux et al. teach that the composition can be administered several times per day and this composition includes

- between 75/Xg and 500/Xg of glucides,

- between 20/X g and 185/X g of lipids,

- between 20/Xg and 225/Xg of proteins,

- sufficient quantities of vitamins, minerals and electrolytes to partially satisfy the daily nutritional needs of a human being, where X is an integer between 2 and 8, equal to the number of rations to be ingested by the patient to satisfy his daily nutritional needs (p. 11, lines 9-17). Examples 1 and 2 are directed to specific polyamine deficient composition.

When the above polyamine deficient compositions are administered to man, it is known to induce a powerful antalgic effect (p. 13, lines 1-4). The antalgic or pain killing effect of the polyamine deficient compositions is demonstrated in the examples beginning at page 21 and continuing though page 23. Please note that the compositions and experiments showing the antalgic effect of these compositions as taught by Moulinoux et al. are identical to those of the instant specification (i.e. the paw

pressure test). As evidenced by the instant specification, pain is a condition in which the NR2-B subunit of the N-methyl-D-aspartate is involved. See page 1, lines 8-15).

It is noted that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See also MPEP 2111.02. In the instant case, the sole active step required by the claims is the administration of a food composition for human consumption which composition comprises a daily food ration containing less than 1600 picomoles of polyamines. Moulinoux et al. teaches this sole active step, namely administering compositions identical to those instantly claimed to humans. Accordingly a syndrome or pathology having increased sensitivity and memorization of pain will be treated.

Response to Arguments and 37 CFR 1.132 Declaration

Applicant's arguments and declaration submitted 6/7/2010 have been fully considered, but are moot in light of the new grounds of rejection necessitated by amendments. However, the Examiner will address any issues still relevant.

Applicant argues that the instantly claimed invention is a new use of a polyamine deficient daily food ration composition and that the disclosure of Moulinoux et al. does not disclose the use of the polyamine deficient food ration as claimed. Specifically

applicant argues that the composition in Moulinoux et al. is used as an analgesic to reduce the activity of nocioceptive pathways whereas the present invention claims the use of the polyamine deficient diet composition as an anti-hyperalgesic and is related to the inhibition of the overactivation of specific facilitatory systems. Applicant included a declaration under 37 CFR 1.132 describing the differences between analgesic effect and anti-hyperalgesic effect. These arguments and the declaration have been fully considered but are not persuasive.

Applicant's arguments and declaration are directed to subject matter which is not currently claimed. As addressed in the above rejection, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See also MPEP 2111.02. In the instant case, the sole active step required by the claims is the administration of a food composition for human consumption which composition comprises a daily food ration containing less than 1600 picomoles of polyamines. Moulinoux et al. teaches this sole active step, namely administering compositions identical to those instantly claimed to humans. Accordingly a syndrome or pathology having increased sensitivity and memorization of pain as recited in the claim will be treated.

The Examiner further notes that the claims as currently presented do not require the composition be administered to a human nor do they require that the human be suffering from a syndrome or pathology having increased sensitivity and memorization of pain and consequently the development of chronic pain. A composition for human consumption could be administered to animals other than humans. As currently presented, the patient population recited by the claims reasonably includes any and every animal having NR2-B subunits on NMDA receptors.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant situation, the prior art teaches the administration of a composition identical to that recited by the claims to a human, which is the sole active step required by the claim.

The examiner also notes MPEP 2131.04 which states that evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. *In re Wiggins*, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973). Accordingly the 37 CRF 1.132 declaration cannot overcome the instant rejection under 35 USC 102.

Conclusion

Claims 1, 13-16, 23-27, 29 and 31-32 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. As addressed above, the rejections have only been modified to the extent necessary to address the newly added claim limitations. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 10 am to 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Ashwin Mehta/
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